MAY 17 2011

K102251

510 (k) Summary of Safety and Effectiveness for DASH knee

Manufacturer:

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Contact Person:	Mr. Alexander Schwiersch

Summary Date: July 12, 2010

Device Name:

Trade name:	DASH knee
Common/Classification Name:	BrainLAB DASH, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
BrainLAB Knee (K073615)
Kolibri Image Guided Surgery System (K014256)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II
Regulation Number: 21 CFR 882.4560
Product Code: OLO

Device Description:
Dash is an image guided surgery system for total knee replacement surgery based on landmark based visualization of the femur and tibia. It is intended to enable operational navigation in orthopedic surgery. It links a surgical instrument, tracked by passive markers to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. DASH knee uses the registered landmarks to navigate the femoral and tibial cutting guides to the optimally position.

DASH knee software registers the patient data needed for navigating the surgery intraoperatively. No preoperative CT-scanning is necessary.

Intended Use:
DASH knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical

structure, such as the skull, a long bone, or vertebra, can be identified relative to the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by DASH knee.

Changes made to the predicate device:

Reduced SW complexity: The spectrum of possible workflows has been reduced to one already contained universal express workflow. Within that express workflow registration steps have been combined with the help of an additional instrument.

Additional instrument: Device for multiple point acquisition on femur condyles. Compared to the predicate device, where femoral landmarks have been calculated out of two surface acquisition steps, regarding landmarks are here acquired directly in one step. In combination with a regarding femoral acquisition page the amount of registration steps has been reduced for the user.

Reduced Platform: Compared to predicate device, the main calculation unit is part of the camera stand. A smaller separated display, represented by an iPod touch, acts an embedded display in the instrumentation for navigation.

Wireless communication between embedded display (iPod touch) and main calculation unit (integrated in camera stand).

Completed verification activities:

Following design verification activities have been per formed to ensure correct system functionality as it has been specified:

The first part of the verification covered the instrument and system accuracy during registration and navigation. The registration values have been compared to external measured reference values.
After the verification of the instruments in combination with the software the verification of the software algorithms itself has been performed.
Part three of the verification includes the testing of all possible workflows to ensure the correct behavior of the system for all possible procedures.
With the knowledge of the above named points the current device has been compared to the predicate device.
The next step was the detailed verification of the signed specifications covering the detailed functionality of buttons for example.
At last the measures against the defined risks of the risk analysis have been tested.

This strategy ensures the verification of basic software algorithms up to specific detailed functionality, the comparison to the predicate device and the safety of the defined measures of the risk analysis. All tests have been successfully completed.

Completed validation activities
Following design validation activities have been performed:

A literature search has been performed to prove safety and effectiveness of BrainLAB computer assisted total knee replacement software. This applies directly to DASH knee, since DASH knee is derived from the previous marketed device BrainLAB knee (K073615).

Non-clinical Validation has been performed to prove the system targets and supplement requirement specifications if necessary. With the help of usability workshops (use labs) OR setups and surgery proceedings have been simulated with plastic bones (sawbones).

Pre-clinical Validation has been performed to confirm/ complete detailed specification for each requirement. Here OR setups and surgery proceedings have been simulated in a cadaver lab. Testing persons went through same procedure like for the non clinical use lab sessions.

To prove that all validation issues are addressed, a final validation has been performed under non clinical conditions.

Substantial equivalence:
Dash knee has been verified and validated according to BrainLAB's procedures for product design and development. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device BrainLAB Knee (K073615) and Kolibri Image Guided Surgery System (K014256).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BrainLAB AG
% Mr. Alexander Schwiersch
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85622 Feldkirchen, Germany

MAY 17 2011

Re: K102251
Trade/Device Name: DASH Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 29, 2011
Received: May 06, 2011

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter D. Pfendler DEPDP

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102251

Device Name: DASH knee

Indications For Use:

DASH knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by **DASH knee**.

Example orthopedic surgical procedures include but are not limited to:
- Total Knee Replacement
- Ligament Balancing

Prescription Use ____X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102251